

# PATENT SPECIFICATION

934,596

NO DRAWINGS.

Inventor:--ANTHONY GEORGE BILOTTI.

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International Classification:--A21c (A61k).

## COMPLETE SPECIFICATION.

### Chewing Gum.

We, WARNER-LAMBERT PHARMACEUTICAL COMPANY, a corporation organized under the laws of the State of Delaware, United States of America, of 201 Tabor Road, Morris Plains, State of New Jersey, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:--

The object of the present invention is to overcome a problem which has existed for many years with regard to the release of active ingredients from slab chewing gum, usually ingredients which are not freely soluble. The said active ingredients is so bound in the gum base, notwithstanding the presence of sweeteners, including sugar and corn syrup, that only a small and ineffective portion of the active ingredient is released during normal chewing of the slab gum.

For many years it has been usual practice in the provision of a chewing gum, carrying active ingredients for nutritional or pharmacological purposes, to deposit the active ingredient upon the exterior of a gum nugget or center, usually with an underlying thin layer of sugar, and to cover the unit with a final layer of hard sugar produced by tumbling the units in coating pans into which saturated solutions of sugar are poured and the water driven out by the action of air, the finished piece being commonly called "candy coated gum". This method of production is costly and does not permit the utilization of slab forms of gum containing such active material.

In the preparation of slab chewing gum, a "base" is first prepared by heating and

blending various ingredients such as natural gums, synthetic resins, waxes, fillers, etc. The completed "base" thus obtained is further blended with corn syrup, sugar and one or more flavoring materials. A complete gum batch having a total weight of 100 lbs., generally consists of 20--30 lbs. of base and 70--80 lbs. of corn syrup and sugar, the major portion of the latter being sugar.

In preparing the chewing gum, the above components are placed in a mixing kettle subjected to mild heat, as for example, somewhat above 100 F., and mixing blades or agitators blend the constituents into a homogeneous dough-like mass. The mass is then unloaded from the kettle, cooled, rolled, scored, set and broken into individual slab pieces.

In practice, the filler constituent of the gum base generally is calcium carbonate. It being insoluble, it is locked in the base during chewing of the slab gum, by the bonding action of the base constituents, and the presence of sugar and corn syrup in such slab gum has no substantial effect in releasing the said insoluble material.

It is an object of the present invention to enable phosphates, chlorophyllins, vitamins, antacids and other active materials, in usual solid powder form, to be incorporated into slab gum, by a prior treatment, so that in high and satisfactory degree they will be released into the oral cavity of the person chewing the slab gum, and hence will have the desired effect. It is a further object to render unnecessary candy coated gum carriers for such active materials, with their greater cost of production, and also greater proportion of sugar.

In accordance with the present invention

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there is provided a slab chewing gum which comprises an insoluble base and particles of a solid active material which is not freely soluble and which tends to be substantially bound against release from the chewing gum in the chewing of the latter, the said solid active material being in powder form and dispersed in the gum base as discrete particles in pulverulent condition individually coated with sugar. The steps leading to individual slabs or sticks are as customary. In chewing the gum slab thus formed, the hard films of sugar encircling the active material particles are very quickly dissolved and they draw out with their solution the active particles themselves to a very high degree.

Specification No. 296,911 discloses a candy-coated chewing gum which has an interior gum nugget containing large particles of sugar incorporating a medicament. According to said Specification a sugar pellet of the order of 20 mesh is coated with a medicament and the pellet size further built up by repeated coatings with syrup until it has attained a larger size. This pellet is then incorporated in a thick sugar coating. In the present invention the individual particles which are coated with sugar and dispersed in the gum base of a slab chewing gum are in pulverulent condition, i.e. are fine particles, for example of the order of 270 mesh size.

To illustrate the improvement, experiments were made using dicalcium phosphate incorporated in several ways into slab chewing gum. Dicalcium phosphate was shown to have important therapeutic value in experiments conducted in Sweden and the United States. The dicalcium phosphate supplements the supply of calcium and phosphate in the saliva and is an effective agent against the acids that cause tooth decay. However, in order to be effective, the dicalcium phosphate must be released into the saliva in sufficient amounts. To demonstrate the difficulties overcome in releasing dicalcium phosphate from slab chewing gum the following experiments were made:—

1. With calcium carbonate mixed with the base, as customary, and the slab gum prepared as specified above, the amount of calcium carbonate released during chewing for about thirty minutes was negligible. When dicalcium phosphate was substituted for the calcium carbonate, release of the phosphate, in the same time of chewing, was about the same as that of the calcium carbonate.

2. When the dicalcium phosphate was mixed with the "sugar phase", i.e., sugar and corn syrup, and then the mixture was blended with the gum base, there was insufficient improvement because after thirty

minutes of chewing slab gum made therefrom, the release of the dicalcium phosphate was in the low range of 10--20%.

3. To the dicalcium phosphate was added about an equal amount of sugar, the two being thoroughly mixed and wet down to coat the particles of phosphate, and then dried. The dry mixture was pulverized, and added to the gum base plus sugar phase so that the coated particles were substantially equally dispersed throughout the base. The ratio was 20% base, corn syrup 20%, and sugar 40% with the addition thereto of the 20% hard sugar coated phosphate powder (1:1) particles. The ingredients as a whole were mixed together in a mixing kettle and carried through customary steps leading to slabs of chewing gum, and the gum tested by chewing for thirty minutes. The release of dicalcium phosphate was nearly 65%.

4. A still further improvement was found by spray drying the same proportion of mixed sugar solution and dicalcium phosphate powder, then pulverizing, and adding the sugar coated fine particles of dicalcium phosphate to the two specified phases, with continued procedure as before. The result was that, in thirty minutes of chewing, the slab gum so formed released 75% of the dicalcium phosphate.

The dicalcium phosphate was selected as one of many useful examples of powdered active materials in general, of which chlorophyllins, powdered vitamins, and antacid powders, are a few, and which lend themselves to our method. The dicalcium phosphate is of itself merely one of a group of phosphates which may be releasably held in slab chewing gum, their equivalents being the mono- and tri-calcium phosphates. The invention, being particularly applicable to water-insoluble medicaments and active constituents in powdered form, is applicable to any active materials in small particle size which become bound in substantial degree by chewing gum.

In the reference made above for the use of a proportion of sugar, as coating for the phosphate, the same in weight as the weight of the phosphate, such a proportion of sugar is not essential, particularly where the method is carried out by spray-drying the phosphate with sugar in solution, it being only necessary to produce on the individual active ingredient particles, hard films of sugar which will, to satisfactory degree, resist rubbing action in the mixing kettle. It will be understood that the term "Slab" is used broadly, inasmuch as while the invention is particularly adapted for the stick or slab types of gum, it is also adapted for different retail units, including the type termed "nuggets".

The invention is particularly useful for

slab chewing gum, in that it utilizes water soluble sugars (e.g. sucrose, dextrose or spray dried corn syrup solids) as the release mechanism for the particles of insoluble active ingredients. The water soluble sugars are common to normal slab chewing gums and thus, by making use of the sugars for release, the characteristics of the gum (e.g. flavor, chew, sweating properties) are not changed as would be the case if equivalent amounts of gelatin sorbitol or gum arabic are used.

WHAT WE CLAIM IS:—

1. A slab chewing gum which comprises an insoluble base and particles of a solid active material which is not freely soluble and which tends to be substantially bound against release from the chewing gum in the chewing of the latter, the said solid active material being in powder form and dispersed in the gum base as discrete particles in pulverulent condition individually coated with sugar.

2. Chewing gum according to Claim 1, in which the solid active material in pulverulent form is dicalcium phosphate.

3. Chewing gum according to Claim 1, in which the solid material in pulverulent form is a fat-soluble vitamin.

4. Chewing gum according to Claim 1, in which the solid material in pulverulent form is an insoluble antacid.

5. Chewing gum according to any one of the preceding claims, in which the coated active particles are substantially equally dispersed throughout the base.

6. A method of preparing a slab chewing gum according to any one of the preceding claims which comprises subjecting a batch of the particles in powder form to the adherent film forming action of a sugar, drying the batch, breaking the batch into individual coated particles and mixing said particles into a chewing gum body which includes such insoluble gum base in such manner that it is distributed throughout the chewing gum body, and then forming same into units for use.

7. A method according to Claim 6, in which the particles of active solid material in powder form are treated with a solution of sugar and then dried.

8. A method of preparing chewing gum according to Claim 6 substantially as herein described.

9. Chewing gum prepared by the method according to any one of Claims 6 to 8.

10. Chewing gum according to Claim 1 as herein described.

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PATENTS SUMMARY

01/05/99

Page 1

Country : Great Britain

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Inventor: Anthony George Bilotti

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Assignee: Warner-Lambert

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Title:

CHEWING GUM

Desc.:

A slab chewing gum that contains particles of a solid active material and a method of preparing the gum are claimed. The solid active material which is not freely soluble and which tends to be bound against release during chewing is in powder form and is dispersed in the gum base as discrete particles coated with sugar. Claimed solid active materials are dicalcium phosphate, a fat-soluble vitamin and an insoluble antacid.

Key Words:

10 CHEWING GUM

25 Pharmaceutical

51 Sucrose

350 GUM BASE

461 Salt, Ions, Metals, Minerals

467 Pharmaceutical Agents

478 Vitamins

504 Mixing/Gum Manufacture

555 Fast or Slow Release/Long Lasting

564 Particle Size

574 Health Benefit

712 Warner-Lambert/American Chicle

804 Great Britain